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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,599	06/07/2005	Allen D. Delaney	KINE-038	3137

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,599	DELANEY, ALLEN D.	
	Examiner	Art Unit	
	BRANDON J. FETTEROLF	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,10,13-15,26 and 41* is/are pending in the application.

4a) Of the above claim(s) *2,3,6,10,13-15,26 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on January 10, 2008 in response to the Restriction Requirement of 7/10/2007 has been entered. Applicant's election with traverse of Group I, claims 1, as specifically drawn to the special technical feature of a method of screening for biologically active agents that modulate a cancer associated protein kinase function, the method comprising combining a candidate biologically active agent with a polypeptide has been acknowledged. The traversal is on the grounds that the present application is a National Stage Filing of an international Application, and is thus governed by 37 C.F.R. 1.475, which states that "An international and a national stage Application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept ("requirement of unity of invention). In particular, Applicants assert that where a group of inventions is claimed in an application, the Requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features, wherein the expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a while, makes over the prior art. As such, Applicants assert that the claims as amended are drawn to the special technical feature of a method of screening using a polypeptide or nucleic acid associated with PCTK3, and claims 1-3, 10 and 13 are generic to and read on the species.

These arguments have been carefully considered, but are not found persuasive.

In the instant case, the Examiner acknowledges that Applicants have amended some of the current claims to methods of screening using a polypeptide or nucleic acid associated with PCTK3, claims 1-3, 10 and 13. However, the Examiner recognizes methods of screening using the polypeptide associated with PCTK3, e.g., SEQ ID NO: 4, does not appear to result in a contribution of the prior art in view of the teachings of Meyerson et al. (The EMBO Journal 1992; 11: 2909-2917) whom teaches a peptide referred to as PCTAIRE-3 which appears to have 100% sequence identity to the claimed sequence of SEQ ID NO: 4 and methods of using the a nucleic acid which encodes said polypeptide for screening (see sequence comparison below, page 2911, Figure 1 and page 2913, Figure 5).

The restriction requirement is therefore deemed to be proper and is made FINAL.

Claims 1-3, 6, 10, 13-15, 26 and 41 are pending.

Claims 2-3, 6, 10, 13-15, 26 and 41 are withdrawn from consideration as being drawn to non-elected inventions.

Claim 1 is currently under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 2/18/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Meyerson et al. (The EMBO Journal 1992; 11: 2909-2917) in view of Yamamoto et al. (International Journal of Oncology 1998; 13: 233-239).

Meyerson et al. teach the identification of a novel family of human cdc2-realted protein kinases. In particular, Meyerson et al. teach a peptide referred to as PCTAIRE-3 which appears to have 100% sequence identity to the claimed sequence of SEQ ID NO: 4 and methods of using the a nucleic acid which encodes said polypeptide for screening (see sequence comparison below, page 2911, Figure 1 and page 2913, Figure 5). Moreover, Meyerson et al. teach that the nucleic acid encoding said peptide is present in MCF-7 human breast adenocarcinoma cell lines (figure 4).

Meyerson et al. does not explicitly teach a method of screening for biologically active agents that modulate PCTAIRE-3 comprising combining a candidate biologically acitve agent with PCTAIRE-3.

Yamamoto et al. teach that cyclin dependent kinases such as cdk2 and cdc2 are overexpressed in colon carcinoma (page 233, 2nd column, 2nd full paragraph). However, Yamamoto

et al. teaches that it remains to be clarified whether cdk2 and cdc2 levels increase in tumorogenesis (page 233, 2nd column, 2nd full paragraph). Hence, Yamamoto et al. teach a method of determining role of cdk2/cdc2 in colon cancer cells comprising contacting said cancer cells with a specific inhibitor of cdk2 and cdc2 and determining the effects on the cells, wherein the inhibitor the growth of the cancer cells (page 236, 1st column, Growth inhibition of colon carcinoma cells with butyrolactone I). Thus, the reference teaches that inhibition of cdk2/cdc2 using a certain drug or antisense nucleotide may be a useful strategy against colon cancer.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the reference so as to determine the role of the peptide as taught by Meyerson et al. in MCF-7 human breast adenocarcinoma cells lines by using a suspected inhibitor of cdc2 in view of the teachings of Yamamoto et al. One would have been motivated to do so because as taught by Yamamoto et al., successful inhibition of a cancer related protein having a role in tumorogenesis leads to a useful strategy for treatment of the disease. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by determining the role of the peptide as taught by Meyerson et al. in MCF-7 human breast adenocarcinoma cells lines by using a suspected inhibitor of cdc2 in view of the teachings of Yamamoto et al., one would clarify the role of PCTAIRE-3 in breast cancer.

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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